

State/Territory: California

STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

California's Medicaid program covers the following transplants: bone marrow, cornea, kidney, heart and liver. Transplant centers must follow the prescribed protocols outlined in Section 1138 (a) of the Social Security Act. State law mandates each general acute care hospital to develop a protocol for identifying potential organ and tissue donors. Participating hospitals must assure that the deceased individual's next of kin are informed of all their options including the option to decline. The hospital's protocol must encourage reasonable discretion and sensitivity to the family circumstances and must take into account the deceased individual's religious beliefs. Finally, the hospital is also required to notify an organ and tissue procurement organization of potential organ donors and cooperate in the procurement of the anatomical gift. Kidney transplant centers must meet Medicare's requirements for facilities, conditions of participation, and conditions of coverage. Except for cornea transplants, all organ transplants require prior authorization to be obtained from a Medi-Cal field consultant. The following is a description of each transplantation and criteria for selection of patients and facilities.

BONE MARROW TRANSPLANT

Bone Marrow Transplant (BMT) is covered for certain types of anemia, leukemia, osteopetrosis, immunodeficiency diseases, lymphomas, Hodgkin's Disease, neuroblastomas, genetic diseases, and Thalassemia. Criteria for selection of patients and facilities are as follows:

A. Patient Selection Criteria:

1. The patient must be less than 50 years old except when a syngeneic donor is available.
2. The patient is one for whom current medical therapy is not as likely as BMT to be curative or to prevent progressive disability or death.
3. The BMT is intended to cure the patient of the disease for which BMT is performed.
4. After the BMT is performed the patient is expected to have a range of physical and social function consistent with activities of daily living.
5. The patient does not have an additional progressive disorder which would otherwise seriously jeopardize survival; i.e., another life-shortening or seriously disabling condition.

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6. A Medi-Cal approved BMT center has evaluated the patient and has recommended a BMT.
7. Either a syngeneic or HLA histocompatible sibling (allogeneic) donor is available or current medical literature has established that a less favorable related donor match, without in vitro treatment of the marrow, produces equivalent results. Except for a three locus match for SCID and Autologous Bone Marrow Transplant (ABMT) for selected high risk cases of Acute lymphoblastic leukemia (ALL) and Acute non lymphoblastic leukemia (ANL), BMT procedures involving in vitro treatment of the donor marrow are not covered. Any subsequent BMT requires prior authorization by a Department medical consultant, based on separate justification and documentation of the reasons for failure of the previous graft(s) and presentation of evidence to establish that the subsequent graft will be successful.

B. Facility Selection Criteria.

1. The facility must be a fully equipped tertiary hospital with:
 - a. a major commitment to teaching and research.
 - b. active hematology/oncology, radiation/oncology, immunology and infectious disease departments, and
 - c. Reverse isolation facilities:
2. The facility must have a successful performance record.
3. It must be documented that there is a need for a BMT Center in the facility's region.
4. The facility must have appropriate patient management plans and protocols, including patient selection criteria and plans for the long-term management and liaison with the patient's family and referring physician.
5. Patients selected for BMT must be reviewed by an interdisciplinary transplant review (or equivalent) committee.
6. The facility must be committed to the performance of at least ten BMT's per year and there is evidence that:
 - a. the facility staff has the appropriate expertise and commitment for participation.
 - b. the facility has an active clinical organ transplant program involving immunosuppressive techniques and reverse isolation and qualified nursing staff trained in these areas.

7. The facility has the capacity and commitment to conduct a systematic evaluation of clinical outcome and costs of BMT.
8. For bone marrow transplants for persons under 21 years of age, the facility must have approval of California Children Services and comply with its standards.

LIVER TRANSPLANT

Liver transplantation (LT) is a Medi-Cal program benefit for the treatment of end-stage liver disease. Related services such as obtaining, preserving and transporting the homograft, evaluation of the candidate, and transporting the candidate when medically necessary are covered subject to prior authorization. Criteria for the selection of patients and facilities are as follows:

Patient Selection Criteria

1. LT is only available for patients in instances where current medical therapy will not prevent progressive disability and death.
2. Current medical therapy will not prevent progressive disability and death;
3. The patient does not have other major system disease (e.g., lung, heart, brain, or renal damage) which would preclude surgery or indicate a poor potential for rehabilitation and there is every reasonable expectation, upon considering all the circumstances involving the patient, that there will be strict adherence to the long-term difficult medical regimen which is required;
4. The LT is likely to prolong life for at least five years and to restore a range of physical and social function suited to activities of daily living;
5. A Kasal procedure (porticoenterostomy) is not indicated or has failed to prevent progressive deterioration;
6. The patient is not in an irreversible terminal state (moribund) and on a life support system;
7. The patient does not have portal vein thrombosis, cancer, bacterial or fungal infection outside the hepatobiliary system, or active abuse of alcohol or other hepatotoxic drugs;
8. The underlying original hepatic disease is not expected to recur and/or to cause substantial disability within a period of five years;
9. The patient does not have multiple uncorrectable severe major system congenital anomalies;
10. The patient has a diagnosis appropriate for LT (see supplemental lists of approved diagnoses, Attachments 3 and 4); and

11. A facility with appropriate expertise has evaluated the patient and has recommended a LT and a facility with a LT service which meets the criteria below has indicated willingness to undertake the procedure.

Facility selection criteria:

1. The facility has available expertise in hepatology, gastroenterology, immunology, infectious disease, nephrology, pulmonary medicine, pediatrics, pathology, pharmacology, anesthesiology, and oncology;
2. The LT program staff has extensive experience and expertise in the medical and surgical treatment of hepatic disease;
3. Transplant surgeons trained in the technique at an institution with a well-established LT program, are available on the staff;
4. The transplantation program has adequate services to provide specialized psychosocial and social support for patients and families;
5. Blood bank services capable of supplying large quantities of blood on short notice are available;
6. Satisfactory arrangements exist for donor procurement services;
7. The institution is committed to a program of at least 25 LTs a year;
8. The center has a consistent, equitable, and practical protocol for selection of patients (at a minimum the above Patient Selection Criteria must be met);
9. The center has the capacity and commitment to conduct a systematic evaluation of outcome and cost;
10. In addition to hospital administration and medical staff endorsement, hospital staff support exists for such a program;
11. The hospital is licensed for renal dialysis and has an active dialysis service;
12. The hospital is licensed for renal transplantation or has an active ongoing organ transplantation program with a tissue laboratory and extensive skills in tissue typing and immunological techniques;
13. The hospital is licensed for open-heart surgery or has demonstrated capability to do hemoperfusion;
14. The facility is a full service tertiary hospital with significant teaching and research functions; and
15. Initial and continuing approval of a LT center requires evidence of a record of success and safety with LT and that the program continues to meet the above criteria. Initial approval as a LT center requires performance of at least 12 LTs with a one-year survival of at least 67 percent.

HEART TRANSPLANT

Heart transplantation (HT) is a Medi-Cal program benefit for the treatment of end-stage heart disease; coverage includes preoperative evaluation, HT surgery and harvesting, preservation, and transportation of the donor heart. Only one HT evaluation per patient may be authorized within a 12-month period and repeat of expensive tests, such as cardiac catheterization, performed outside the HT center, will not be covered unless the medical necessity is documented. All services related to HT require prior authorization. Patient and facility selection criteria are as follows:

Patient Selection Criteria:

1. The patient is one for whom current medical therapy will not prevent progressive disability and death and the expectation of survival does not exceed a few months;
2. The HT is likely to prolong life for at least five years and to restore a range of physical and social function suited to activities of daily living;
3. The patient does not have other major system disease (e.g., lung, liver, brain, or renal damage) which would preclude surgery or indicate a poor potential for rehabilitation;
4. There is reasonable expectation, upon considering all the circumstances involving the patient, that there will be strict adherence to the long-term difficult medical regimen which is required;
5. The patient is not in an irreversible terminal state (moribund);
6. The patient does not have any active infection, a recent pulmonary infarct, insulin-dependent diabetes mellitus, evidence of elevated and fixed pulmonary vascular resistance, or a positive cross-match between recipient serum and donor lymphocytes;
7. The patient has a diagnosis of:
 - a. End-stage congestive heart failure, or
 - b. (In selected cases) inoperable congenital heart disease, or cardiovascular trauma, or cardiovascular tumor; and
8. A facility with appropriate expertise has evaluated the patient and has recommended a HT and a HT facility is willing to perform the operation.

Criteria for approval of a facility as an HT center:

1. The facility must be a fully equipped tertiary hospital with major teaching and research programs and with a licensed, active, large scale open heart program (minimum of 500 cardiac catheterizations per year), an established program of percutaneous transvenous endomyocardial biopsy, and an identified, stable surgical team that has demonstrated low mortality rates in an active open heart program involving at least 250 procedures per year);
2. Initial and continuing approval of a HT center requires it to have significant experience with HT and a record of acceptable success and safety. Prior to consideration of any application by an institution to be designated as a HT center under the Medi-Cal program, there must be submitted evidence of performance of at least 10 per year. Costs must not be significantly higher than those at established HT centers.
3. The facility must have patient selection criteria at least as strict as those listed above and requests for Treatment Authorization Requests (TARs) must first be approved by the facility's interdisciplinary transplant review committee or equivalent committee(s).
4. The facility must have adequate patient management plans and protocols, including plans for the long term management of the patient and liaison with the patient's referring physician;
5. The facility is committed to performance of at least 25 HTs a year and there is evidence that:
 - a. The commitment of the facility includes all departments and is at all staff levels;
 - b. Facility staff has both the expertise and the commitment for participation in the medical, surgical and other relevant areas including cardiology, cardiovascular surgery, anesthesiology, immunology, infectious diseases, nursing, neurology/neurosurgery, oncology (particularly for the diagnosis and treatment of lymphoproliferative disease) and social services;
 - c. The component staff teams are integrated into a comprehensive team with clearly defined leadership and corresponding responsibility;
 - d. The facility has an active clinical organ transplantation program (other than heart) involving appropriate immunosuppressive techniques and a satisfactory record of efficacy and safety;
 - e. The nursing staff is trained in the special problems of managing immunosuppressed patients;
 - f. The neurology/neurosurgery group is available for donor selection procedures necessary and to establish brain deaths;

- g. The legal officer is familiar with transplantation laws and regulations; and
 - h. There are adequate logistical plans for organ procurement meeting legal and ethical criteria, as well as yielding viable transplantable organs in reasonable numbers;
- 6. The facility's commitment to research, development and transmission of knowledge is such that there is the capacity to conduct a systematic evaluation of clinical outcome and costs; and
 - 7. The location of the hospital does not duplicate the availability of the HT service in a given geographic area, but rather, improves access to the service in other geographic areas.
 - 8. For additional HT centers to be designated, the number of patients needing HT and for whom donor organs are available must exceed the capacity of existing HT center(s).

KIDNEY TRANSPLANT

Renal transplantation is available for individuals who have chronic irreversible renal insufficiency which limits life expectancy to a few weeks or months. Criteria for patient and facility selection are as follows:

Patient Selection Criteria:

- 1. The patient must be free of major infections and able to withstand the operational trauma after maximum improvement from preoperative care.
- 2. The patient must have a relatively normal lower urinary excretory tract.
- 3. There must be documentation that a satisfactory donor is available who has passed examination, renal function tests, and histocompatibility tests.
- 4. There must be evidence of chronic irreversible renal insufficiency such as evidence of azotemia, creatine clearance of less than 20 ml. per minute, findings from renal function tests or histocompatibility tests.

Facility Selection Criteria

Renal Transplant Centers must be a specialized unit of a hospital and be capable of providing acute dialysis, renal transplantation, and peritoneal dialysis or other means for removing toxic or excessive waste products from the blood.

The hospital shall meet the following requirements:

- 1. At least fifteen transplants should be performed per annum to demonstrate capability and high quality.

2. The hospital shall offer both living related donor and cadaver donor transplant services.
3. The hospital shall coordinate and with other facilities providing care for end-stage renal disease and accept referrals from those which do not.
4. The hospital must operate under a written hepatitis control program incorporating the recommendations of Report 33, January 1971, of the Hepatitis Surveillance Program of the Center for Disease Control, Public Health Services, Atlanta, GA 30333.
5. The hospital must also be equipped to directly provide respiratory therapy, angiography, nuclear medicine, and immunofluorescence studies. It must also have a twenty-four hour laboratory capability of performing the following determinations: C.B.C., B.U.N., creatinine, platelet count, blood typing and cross matching, blood gas analysis, blood pH, electrolytes, serum glucose, coagulation tests, spinal fluid examination, and urinalysis.

CORNEA TRANSPLANTS

The Medi-Cal program covers cornea transplants when medically necessary. Patient selection is determined by a licensed Ophthalmologist and surgeon. Cornea transplantation can be done either on an inpatient or outpatient basis depending on the needs of the patient. Hospitals and clinics must meet federal and state licensing standards. Ophthalmologists and surgeons must be licensed in accordance with their respective state boards. Their practices are reviewed by the State Board of Medical Quality Assurance.

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